

**REMARKS**

As an initial matter, the applicants would like to thank the Examiner as well as primary Examiner Andrew Johns for the courtesies extended during the telephonic interview of April 21, 2010 ("Interview"). During that Interview, agreement was reached that new claims 45-52 were patentable over the art of record, though the Examiner indicated that a new search would be necessary before those claims could be allowed. Also, during the Interview, the Examiner indicated that, if the new search results in new art being uncovered which could result in rejection of one or more of the new claims, the Examiner would call the applicants' representative to discuss possible amendments which could overcome that art before issuing an office action. The remarks set forth below summarize the discussion during the Interview, and explain why the claims (both those discussed during the Interview and new claims 53-56) should be allowed in their current form.

**Claims 1-25**

In the office action mailed January 28, 2010 ("Office Action"), the Examiner indicated that claims 18-22 would be allowable if rewritten in independent form including all limitations of the base claim (claim 1) as well as any intervening claims (which there were none, since claim 18 depended directly from claim 1). In response, while not conceding that claim 1 in the application as originally filed was properly rejected, the applicants have amended claim 1 to include the limitations which were previously recited in claim 18. Claim 18 itself has been canceled. Claims 19-21, which previously depended from claim 18, have been amended to depend directly from claim 1. As a result, the applicants request that amended claim 1, as well as claims 2-17 and 19-25 which depend therefrom, be allowed, as those claims now include the subject matter of claim 18 which was indicated as being allowable.

**Claims 45-50**

Claims 45-50 are directed to an apparatus which comprises a program stored in memory and operatively configured to identify a plurality of spinal structures in a composite midline sagittal image volume by iteratively searching for a predefined search number of spinal structures between a patient's axis (C-2 vertebra) and sacrum. Claim 45 (the base claim for claims 45-50) specifically recites that the composite midline sagittal image volume includes at

least a portion of all interspaces and vertebrae between the patient's axis (C-2 vertebra) and sacrum. During the Interview claim 45 was discussed and distinguished from U.S. published application 2003/0086596 ("Hipp"), the primary reference cited in the Office Action. In particular, it was pointed out that Hipp, rather than searching a composite midline sagittal image volume which includes at least a portion of all interspaces and vertebrae, appears to focus on a very specific region of interest in a much smaller portion of a patient's body.<sup>1</sup> Hipp also does not appear to use the same search for a predefined search number of spinal structures as recited in claim 45. Additionally, none of the other references cited in the Office Action appear to include any teachings which can address the deficiencies of Hipp. As a result, it was agreed during the Interview that claim 45 is allowable over the art of record. Accordingly, the applicants request that claim 45, as well as claims 46-50 which depend therefrom, be allowed in their current form.

Claim 51

Claim 51 is directed to an apparatus comprising a program which is configured to create a medical image from a CT image data set using multiple reconstruction algorithms optimized for different types of tissue, and to cause a composite image to be displayed where portions of the composite image corresponding to different tissue types are created using the algorithms optimized for those tissue types. During the Interview, the applicants addressed the relationship of claim 51 to the art of record, particularly the article A Knowledge-Based Approach to Automatic Detection of the Spinal Cord in CT Images ("Archip"), which was cited in the Office Action as teaching

display a visual representation of the medical diagnostic image using a first contrast and a second contract, wherein the first contrast is used for portions of the visual representation corresponding to bone and wherein the second contract is used for portions of the visual representation corresponding with soft tissue.<sup>2</sup>

The applicants explained that the cited disclosure of Archip differed from the language of new claim 51 at least because it did not address using different CT reconstruction algorithms

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<sup>1</sup> See, e.g., Hipp, ¶ 42 ("With respect to the tracking of vertebrae in radiographic (x-ray) images, this technique involves identifying a small region 17 within a source image (FIG. 4a) that contains the vertebra or object of interest. This region containing the object to track is called a search model or template. The search model is used to find similar regions in subsequent 'target' images that contain identical information as the model 20 (FIG. 5).").

<sup>2</sup> Office Action at 16.

optimized for different tissue types, and because it did not disclose presenting a composite medical image where different portions of the composite image are created using different reconstruction algorithms. Instead, it discloses only that both bone and soft tissue can exist in medical diagnostic images, and that, in such images, bone tissue can be displayed in white, while soft tissue is displayed in gray.<sup>3</sup> As none of the other art of record includes disclosure which is more relevant to claim 51 and can be used to remedy the deficiencies of Archip, it was agreed that claim 51 cannot properly be rejected over the art of record. Accordingly, the applicants request that claim 51 be allowed in its current form.

In addition to analysis of the substance of claim 51 and its relationship to the art of record, the discussion during the Interview also addressed the possibility of issuing a restriction and requiring the applicants to cancel new claim 51 on the theory that a different invention was elected by presentation of the claims in the application as originally filed. In response, without conceding that claim 51 is directed to a different invention from what was previously claimed, the applicants noted that such a restriction would only be proper if examining new claim 51 together with the other claims would result in a serious burden on the Examiner.<sup>4</sup> The applicants also noted that, given the similarity between new claim 51 and the technology of the claims in the application as originally filed (particularly dependent claim 24), there was no reason that such a serious burden would exist. As a result, the applicants request that claim 51 be examined on its merits, and allowed in its present form.

#### Claim 52

Claim 52 is directed to a method which comprises applying a skin surface marking surface to an external surface of a portion of a patient's body selected to be imaged wherein the system comprises a localizer comprising a grid and a slice indicator. Claim 52 also recites that the method comprises determining a unique axial and sagittal location in a medical diagnostic

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<sup>3</sup> Office Action at 16, citing Archip as teaching:

That both bone and soft tissue exist in medical diagnostic images [image slices], and provides visual representation of the different contrast that is used for bone tissue [white areas in Figures 1 and 6], in contrast with soft tissue [gray areas in Figures 1 and 6], and further teaches using the different HU levels to threshold out the appropriate tissue type  
(bracketed text in original).

<sup>4</sup> See MPEP 803 ("If the search and examination of all the claims in an application can be made without serious burden, the examiner must examine them on the merits, even though they include claims to independent or distinct inventions.").

image, and correlating that location with a location in the patient's body based at least in part on visual observation of the grid from the localizer. During the Interview, claim 52 was distinguished from the cited art, particularly focusing on U.S. patent 6,011,061 ("Lai") and U.S. published patent application 2006/0241368 ("Fichtinger"), which were cited in the Office Action against a claim from the original application which included a localizer comprising a grid.<sup>5</sup> During the Interview, it was pointed out that Fichtinger clearly differs from the method of claim 52 for at least the reason that Fichtinger appears to disclose an imaging probe which would be inserted into a patient to obtain diagnostic images, not a grid with slice indicator that is applied to an external surface of a patient. This can be seen at least in figure 15 of Fichtinger, reproduced below:

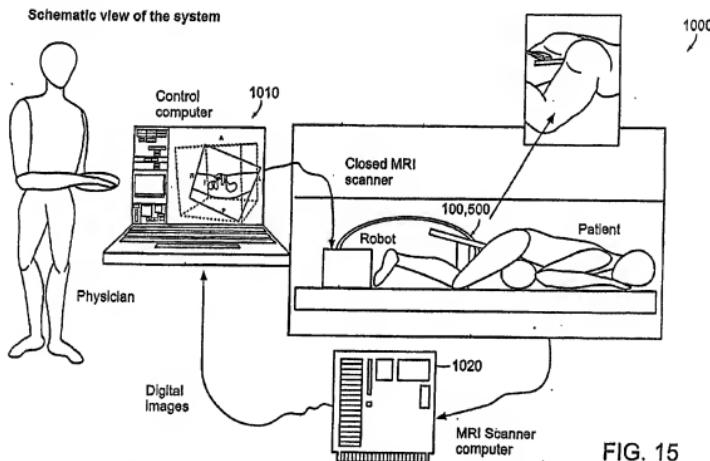


FIG. 15

With respect to Lai, that reference teaches external application of a rubidium chloride preparation for the purpose of treating various health disorders, such as musculoskeletal, neural

<sup>5</sup> Office Action at 24, applying Lai and Fichtinger to original claim 39.

and respiratory disorders.<sup>6</sup> Such topical application of a rubidium chloride preparation cannot remedy the deficiencies of Fichtinger for at least the reason that externally applying the probe of Fichtinger would rob that probe of its utility, while modifying the probe to include a grid as recited while still applying it internally would both fail to teach the method of claim 52 and provide an exceedingly uncomfortable experience for the patient being probed. Further, the other art of record cannot address the weaknesses of the combination of Lai and Fichtinger cited in the Office Action. As a result, it was agreed that claim 52 is allowable over the art of record. Accordingly, the applicants request that claim 52 also be allowed in its current form.

In addition to analysis of the substance of claim 52 and its relationship to the art of record, the discussion during the Interview also addressed the possibility of issuing a restriction and requiring the applicants to cancel new claim 52 on the theory that a different invention was elected by presentation of the claims in the application as originally filed. In response, the applicants noted that, given the similarity between new claim 52 and the claims in the application as originally filed, particularly claim 39, restricting and requiring cancellation of claim 52 would be improper. After examining claim 39, the Examiner, as well as Primary Examiner Andrew Johns, agreed that restriction of claim 52 would not be proper. Accordingly, the applicants request that claim 52 be examined with the other claims presented in this application, and allowed in its current form.

#### Claims 53-55

With respect to claim 53, the applicants submit that that claim (which was not discussed during the Interview) is clearly patentable over the cited art because, as set forth in the discussion of claim 45, Hipp (the primary reference cited for automatically identifying spinal structures in a medical diagnostic image) appears to focus on analysis of a very specific region in a small portion of a patient's body. By contrast, claims 53 and 54 (the parent claim for claim 55) recite

- (b) executing a program, which is stored in a computer memory, by a processor for:
  - (i) generating a composite midline sagittal image volume of the neuro-axis by combining two or more medical diagnostic images from the plurality of medical diagnostic images, wherein the **generated composite midline sagittal image volume includes at**

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<sup>6</sup> See Lai, Abstract ("Various methods of treating the musculoskeletal, neural and respiratory disorders in a patient are disclosed wherein a preparation containing rubidium ions, preferably in the form of rubidium chloride, are administered externally and internally to a patient.").

**least a portion of all interspaces and vertebrae between the patient's axis (C-2 vertebra) and sacrum; and,**

(ii) automatically identifying...

(emphasis added). As a result, the applicants submit that claims 53-55 cannot properly be rejected over the cited art, and should instead be allowed in their current form.

Claim 56

With respect to claim 56, while that claim is newly presented, the applicants submit that its patentability over the art of record can be established by examining the Office Action's rejection of claim 24. As originally filed, claim 24 was directed to an apparatus comprising a screen, and recited a program operable to display a visual representation of a medical diagnostic image using a first contrast and a second contrast, wherein the first contrast is used for portions of the visual representation corresponding with bone and wherein the second contrast is used for portions of the visual representation corresponding with soft tissue. In rejecting claim 24, the Office Action stated that the visual representation of that claim was taught in Archip, focusing particularly on figures 1 and 6 in that reference.<sup>7</sup> Figures 1 and 6 of Archip are set forth on the following page.

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<sup>7</sup> See Office Action at 15-16.

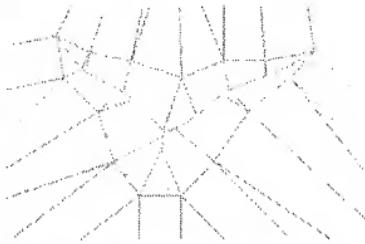


(a)

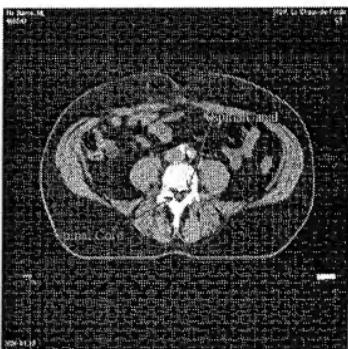


(b)

Fig. 1. The two types of slices. (a) Spinal canal completely surrounded by bone. (b) Spinal canal partially surrounded by bone.



(a)



(b)

Fig. 6. MIC in the spinal canal polygon. (a) The Voronoi Diagrams used for detection of the medial axis, which gives the center of MIC. (b) This solution applied for spinal cord detection.

Archip, figures 1 and 6.

As can be seen from those figures, the cited portion of Archip, at most, teaches that bone and soft tissue can be included in a single image where they are differentiated by the use of white and grey pixels. Without conceding that claim 24 was properly rejected over those sections of Archip, the applicants submit that claim 56 could clearly not be rejected based on that reference, because it recites imaging technology which is substantially more sophisticated than shown in Archip. For example, clause (b) of claim 56 recites:

executing a program, which is stored in a computer memory, by a processor, wherein the program is operatively configured to decompose water and fat components of the medical diagnostic image and cause the medical diagnostic image to be presented on a display wherein structures containing only water are

displayed in gray scale and structures containing fat in the displayed medical diagnostic image are distinguishable from other aspects based on color.

The applicants note that this decomposition of water and fat components of an image, followed by the display of an image where those components are distinguishable based on color is clearly different from the cited diagrams of Archip. Accordingly, like claims 1-55, the applicants submit that claim 56 cannot properly be rejected based on the art of record, and should be allowed in its current form.

Other Issues

In addition to addressing the relationship between the originally presented claims and the art of record, the Office Action also presented several objections to the claims and specification. In particular, on page 2, the Office Action objected to the specification because “Figure 16B is not properly described in the ‘Brief Description of the Figures’ and because “the use of element ‘block 46’ with respect to Figure 1 appears to be a typo, as Figure 1 does not have any element with this label.”

In response, the applicants note that it appears that, while the Examiner has examined the correct claims, the objections to the specification and drawings are based on an analysis of the wrong documents. In particular the applicants believe that the objections are based on analysis of application PCT 2005/008311, from which the current application claims priority, rather than from the current application itself. In support of this position, the applicants present figure 1 from PCT 2005/008311, as well as figure 1 from the current application.

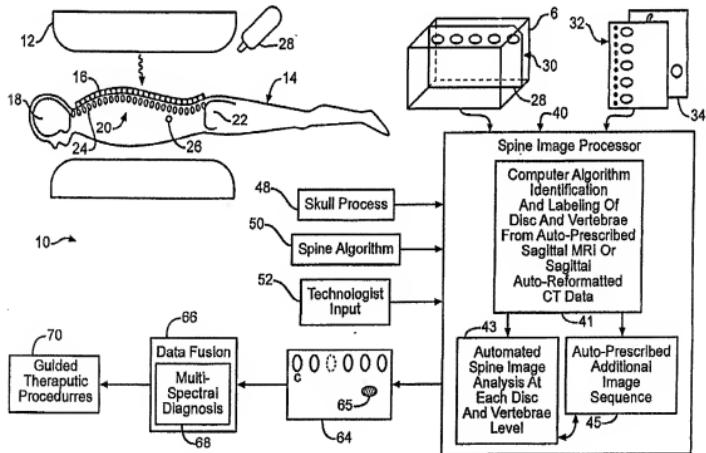
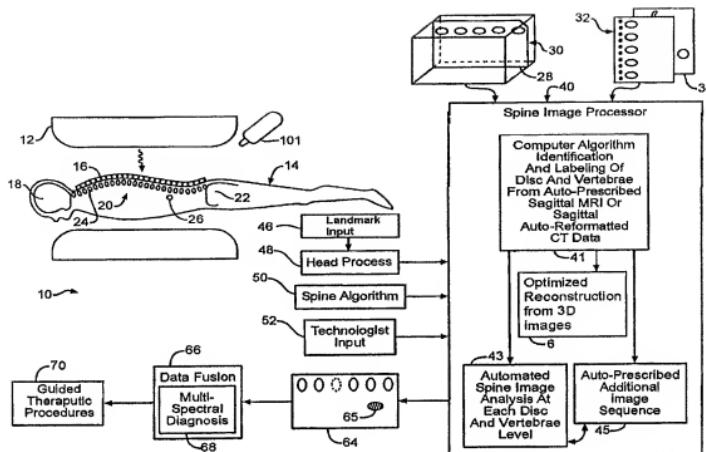


Figure 1, PCT 2005/008311

As can be seen, Figure 1 from PCT 2005/008311 differs from figure 1 in the current application in that the PCT version of figure 1 does not include box 46: Landmark Input. Thus, the fact that the Office Action stated that “the use of element ‘block 46’ with respect to Figure 1 appears to be a typo, as Figure 1 does not have any element with this label” strongly indicates that the Examiner based her objections on the PCT application, rather than on the application which corresponded to the claims under examination.

When the apparent focus on the incorrect application was brought to the Examiner’s attention, the Examiner indicated that it may have been proper to focus on the PCT application, because this application was identified as a filing under 35 U.S.C. § 371. However, based on a review of the application’s history, the applicants submit that the identification of the current application as a filing under 35 U.S.C. § 371 is incorrect. The fee transmittal form and the declaration for the application both indicate that the application is not a 371 application by listing a title (Automated Neuroaxis (Brain and Spine) Imaging with Iterative Scan Prescriptions, Analysis, Reconstructions, Labeling, Surface Localization and Guided Intervention) which is different from the title on the PCT application (Automated Spine Survey Iterative Scan Technique (ASSIST)). Similarly, the declaration lists an inventor (Judd Storrs) who wasn’t present on the PCT application, and all documents indicate that the number of claims (44) is different from the number of claims present in the PCT application. Indeed, with the exception of an anomalous indication that that the application was filed with 371 fees in the fee worksheet, all documents filed by the applicants desired to proceed with a normal application filing claiming priority from the PCT application, rather than with a 371 national stage entry.

Under both the regulations and the MPEP, for an application to be a 371 application, it must be *clearly* identified as a 371 application.<sup>8</sup> In the event that there are conflicting instructions as to whether an application is a 371 application, the application is treated as a filing

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<sup>8</sup> MPEP 1893.03(a):

Applicant's initially deposited application must be clearly identified as a submission to enter the national stage under 35 U.S.C. 371...Otherwise, unless the submission is clearly identified as a submission pursuant to 35 U.S.C. 154(d)(4) for the purpose of obtaining provisional rights, the application will be treated as an application filed under 35 U.S.C. 111(a).

37 C.F.R. 1.495(g):

The documents and fees submitted under paragraphs (b) and (c) of this section must be clearly identified as a submission to enter the national stage under 35 U.S.C. 371. Otherwise, the submission will be considered as being made under 35 U.S.C. 111(a).

under 35 USC § 111.<sup>9</sup> As a result, to the extent that any references to 35 U.S.C. § 371 made at the time of the initial filing are treated as instructions to treat the application as a 371 application, the instructions that the applicants intended to proceed with the application titled Automated Neuroaxis (Brain and Spine) Imaging with Iterative Scan Prescriptions, Analysis, Reconstructions, Labeling, Surface Localization and Guided Intervention, having 44 claims, and inventors Ken Weiss and Judd Storrs should have been treated as creating a conflict that would cause the application to be treated as a filing under 35 U.S.C. § 111.

When the above was brought to the attention of the Examiner, she suggested that the applicants contact the office of PCT legal administration, and file a separate document requesting that the apparent mishandling of the application be corrected. When the applicants contacted the office of PCT legal administration, the office of PCT legal administration recommended filing a petition under 37 C.F.R. 1.182 to have the situation addressed. Accordingly, the applicants have prepared the requested petition and are submitting it herewith. Because it is believed that the current objections to the specification are the result of the Examiner analyzing the PCT application, and because the applicants are submitting the necessary documents to have the apparently erroneous identification of the application as a 371 filing corrected, the applicants request that the objections to the specification be reconsidered and withdrawn pending resolution of the application status issue. The applicants also request that this application be referred by the Examiner to the office of PCT legal administration, as MPEP 1893.03(a) states that “Applications that have been processed under 35 U.S.C. 371 and later found by the examiner to contain conflicting instructions should be forwarded to the Office of PCT Legal Administration for resolution.”

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<sup>9</sup> MPEP 1893.03(a) (“if there are any conflicting instructions as to whether the filing is under 35 U.S.C. 111(a) or 35 U.S.C. 371, the application will be accepted as filed under 35 U.S.C. 111(a).”).

**CONCLUSION**

In light of the amendments and remarks made herein, it is respectfully submitted that the claims currently pending in the present application are in form for allowance. Accordingly, reconsideration of those claims, as amended herein, is earnestly solicited. The applicants encourage the Examiner to contact their representative, William S. Morriss at (513) 651-6915 or [wmorriess@fbtlaw.com](mailto:wmorriess@fbtlaw.com).

The Commissioner for Patents is hereby authorized to charge any deficiency or credit any overpayment of fees to Frost Brown Todd LLC Deposit Account No. 06-2226.

Respectfully submitted,  
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